APPENDICES

Appendix A: Account of Events Related to Health Concerns of Gulf War Veterans

Reporting of Gulf War Illnesses and U.S. Governmental Response

During and after service in the Gulf War, some U.S. veterans began to experience adverse health effects. In April, 1991, while troops were still returning home, Congress passed legislation (Public Law [PL]102-25) requiring the Secretary of Defense and the Secretary of Veterans Affairs to:

- assess needs for rehabilitative services for veterans experiencing PTSD, and describe programs and resources available to meet those needs ;
- describe plans for treatment of veterans experiencing PTSD;
- assess needs for additional resources to provide treatment; and
- describe plans for coordination of treatment services for PTSD between the DoD and the DVA (IOM, 1996b).

In response to general concerns about possible health effects of exposure to oil well fires in the Persian Gulf, DVA established the PGHR in April, 1991 to provide clinical examinations for veterans concerned about illnesses that may be related to Gulf War service. This registry was later mandated in PL 102-585 as the DVA Persian Gulf War Veterans Health Registry, to include all U.S. military personnel who served in the Gulf. PL 102-585 also expanded previous legislation (PL 102-90 of December, 1991) to require that the DoD registry of troops exposed to burning oil well fires include all veterans who served in the Southwest Asia theater of operations during the Gulf War (IOM, 1996b). DVA's PGHR established referral centers in Washington, D.C., Houston, Texas, Los Angeles, California, and Birmingham Alabama. In June, 1994, DoD also started a CCEP for active duty troops modeled after DVA's referral center examinations (IOM, 1996b).

Concerns about unusual illnesses among Gulf War veterans arose initially through reports by individuals and then through "outbreak" studies of groups of soldiers who reported a high rate of a variety of nonspecific symptoms, including fatigue, joint pain and stiffness, disturbed or unrefreshing sleep, some gastrointestinal complaints, and a variety of complaints suggestive of mood and musculoskeletal disorders (IOM, 1996b; U.S. Senate, 1998). The set of nonspecific symptoms reported by Gulf War veterans, which also includes memory problems, shortness of breath, and impaired concentration, has not been associated with a characteristic set of clinical signs (Joseph et al., 1997; 1998). Estimates of veterans who reported illnesses possibly resulting from Gulf War service range from a few thousand within one to two years after the war, increasing to 49,000 by 1995 and more than 100,000 in 1997 (Joseph et al., 1998). There have also been concerns about possible occurrences of sudden death, various illnesses, and birth defects in children of veterans (Joseph et al., 1998).

Review Panels and Groups

In response to White House and Congressional interest and involvement during initial actions undertaken by DVA and DoD, several committees and special groups were established to review, inspect, or evaluate various aspects of health issues related to Gulf War veterans. Following are descriptions of the work of some of these review groups.

In May, 1993, DVA convened a meeting of an informal panel of experts that was subsequently chartered as the *Persian Gulf Expert Scientific Committee* to advise the DVA about medical findings affecting Gulf War veterans. The committee was charged to:

- review all aspects of patient care and medical diagnoses;
- provide professional consultation as needed; and
- advise on research and development, veterans benefits, and training for patients and staff.

The committee has had numerous meetings since its inception; the most recent meeting was in the spring of 1998.

In 1993, the DoD established a panel of non-governmental experts called the *Defense Science Board Task Force on Persian Gulf War Health Effects* to review:

- all available intelligence and reports of chemical or biological agent detection or exposure during the Gulf War;
- scientific and medical evidence relating to exposure to nerve agents at low levels and possible long-term effects; and
- other potential health consequences resulting from low-level chemical exposure, environmental pollutants, Kuwaiti oil fires, endemic biologics or other health hazards attributed to Gulf War service.

The 1994 conclusions and recommendations of this group are briefly summarized as follows [see DSB (1994) for full report of findings, conclusions, and recommendations]:

- there was no persuasive evidence that any of proposed etiologies caused chronic illness on a significant scale in the absence of acute injury at initial exposure;
- there was “no scientific or medical evidence that either chemical or biological warfare was deployed” against U.S. forces or “that there were any exposures of U.S. service members to chemical or biological warfare agents in Kuwait or Saudi Arabia”;
- the evidence, at the time of review, was insufficient “to support the concept of any coherent syndrome”, but research on veterans reporting a range of symptoms without a clear-cut diagnosis should be coordinated with ongoing studies of chronic fatigue syndrome in civilian populations;
- more epidemiological research was needed to determine possible associations between health symptoms and any specific aspect of the Gulf War experience;
- DoD, in coordination with DVA, “needs substantial improvements in pre- and post-deployment medical assessments and data handling”;

- clinical treatment of Gulf War veterans with illnesses should be directed at the symptoms presented, and controlled treatment protocols "might assist in carving out specific syndromes from the broad range of symptoms noted"; and
- further research is needed on the long-term health consequences of exposure to chemical or biological weapons, because of the possibility that these agents may be used in future wars.

In 1994, a National Institutes of Health (NIH) Technology Assessment Workshop, *The Persian Gulf Experience and Health*, was held, sponsored by the NIH Office of Medical Applications of Research, the Department of Health and Human Services, the DoD, the DVA, and the Environmental Protection Agency. Based on presentations and discussions at the workshop, a panel of non-government experts prepared a written statement in response to four key questions and arrived at five general conclusions as follows [see NIH (1994a,b) for the full statement of the workshop panel]:

- "The complex biological, chemical, physical, and psychological environment of the Persian Gulf theater of operations appears to have produced complex adverse health effects in the primary military personnel."
- "No single disease or syndrome is apparent, but rather multiple illnesses with overlapping symptoms and causes. Some of these diagnoses or illnesses can be sorted out by rigorous diagnostic, medical, and epidemiological procedures. Others may only be characterized after further research is conducted."
- "A collaborative government-supported program has not been established. Evaluation of undiagnosed Persian Gulf illnesses has not followed a uniform protocol across military branches, VA facilities, and civilian physicians."
- "This has led to imprecise description of diseases and/or symptoms, uncertainties about underlying prevalence rates, and inconsistent treatments. Well-designed epidemiologic studies have not been conducted to link the illnesses of the military personnel with exposures in the Gulf theater of operations. The absence of such studies has hampered the development of an appropriate case definition."
- "Chronic symptoms of viscerotropic leishmaiasis and posttraumatic stress disorders were found to be compatible with some of the unexplained illnesses. The proportion of these illnesses attributable to leishmaniasis and PTSD is unknown at this time, however."

PL 102-585 directed DVA and DoD to establish an agreement with the Institute of Medicine (IOM) of the National Academy of Sciences to review the collection and maintenance of data on health consequences of the Gulf War, consider reported health outcomes, and recommend appropriate studies. The IOM established several panels of experts: *the Committee to Review the Health Consequences of Service During the Persian Gulf War; the Committee on the Evaluation of the DoD Comprehensive Clinical Evaluation Program;* and *the Committee on the Evaluation of the Department of Veterans Affairs Uniform Case Assessment Protocol*. More recently formed IOM committees, whose work is ongoing, include the *Committee on Health Effects Associated with Exposures during the Persian Gulf War* (IOM, 1998a), and the *Committee on Measuring Health Status of Persian Gulf Veterans* (IOM, 1998b).

The IOM *Committee to Review the Health Consequences of Service During the Persian Gulf War* was established to:

- C review DOD and DVA efforts to collect and maintain health data on Gulf War veterans;
- C recommend improvements to the collection and maintenance of such data; and
- C recommend epidemiological research to be undertaken to better determine the health consequences of Gulf War service.

The committee published findings and recommendations in two reports (IOM, 1995; 1996a). In 1996, the Committee made 16 recommendations to the DoD and the DVA, summarized briefly as follows (see IOM (1996a) for full report of the committee's findings and recommendations):

- C establish uniform medical information systems that include an electronic medical record for each service person;
- C conduct studies to identify risk factors and develop better treatment methods for stress-related psychiatric disorders in military personnel;
- C conduct longitudinal follow-up studies of the mental health of Gulf War veterans, after peer-review of study methods;
- C improve military medical preparedness, for future deployments, to respond to physical and environmental exposures in the specific theater of operation;
- C support research to determine whether different or adverse health consequences are associated with reserves, National Guard, or regular troops;
- C compare the mortality experience of Gulf War-deployed veterans with non-deployed veterans for as long as 30 years;
- C conduct studies to discern the reasons for excess mortality from unintentional injury among Gulf War veterans;
- C evaluate and expand the Defense Medical Epidemiological Database;
- C complete development of information systems regarding unit locations during the Gulf War and environmental conditions;
- C assess the ability of troop-location information systems to evaluate troop health consequences;
- C ensure that studies of health effects of deployment evaluate gender-specific parameters;
- C conduct studies of health consequences of men and women serving together in the military;
- C complete and publish results of epidemiological studies conducted by the Naval Health Research Center, of the DVA National Health Survey, and of studies analyzing DVA PGHR data.
- C strengthen the epidemiological capabilities of the U.S. armed forces;
- C adopt a policy that results from DoD- and DVA-sponsored research be reported in a timely manner in the peer-reviewed scientific literature; and
- C publicly announce requests for research proposals related to Gulf War illnesses, and subject all proposals to review by panels of appropriately qualified experts.

In 1996, the IOM *Committee on the Evaluation of the DoD Comprehensive Clinical Evaluation Program (CCEP)* provided an overall assessment of the CCEP, and made numerous

recommendations to the DoD. The committee made the overall conclusion that "*the systematic, comprehensive set of clinical practice guidelines set forth in the CCEP are appropriate*." The committee further concluded that *the interpretation that "the signs and symptoms in many patients can be explained by well-recognized conditions that are readily diagnosed and treatable" is a more likely interpretation of the information collected by the CCEP, than the interpretation that "a high proportion of the CCEP patients are suffering from a unique, previously unknown 'mystery disease'."* Selected recommendations to the DoD are briefly described as follows [see IOM (1996b) for full report of findings, conclusions and all recommendations]:

- C revise protocols to allow the majority of patients to receive a final diagnosis by Phase I;
- C continue referral of subgroups of patients whose illnesses are difficult to diagnose;
- C develop guidelines identifying Phase I patients who would benefit from psychiatric evaluation;
- C provide more detailed information on specific diagnoses in future reports;
- C do not view CCEP results as estimates of the prevalence of disability from Gulf War service;
- C there is a lack of clinical evidence of a unique "Persian Gulf Syndrome";
- C improve standardization diagnostic criteria and provide more details in recording diagnoses (many specific recommendations for specific diagnostic categories were given and are not described herein);
- C continue ongoing, periodic public release of results of analysis of CCEP information;
- C compare and coordinate methods and clinical results of the CCEP with the DVA's Uniform Case Assessment Protocol;
- C acknowledge the serious limitations of the CCEP data for epidemiological purposes; and
- C compare and contrast the types of health effects in individuals from special Gulf War units known to have special exposures to specific risk factors with health effects noted in other units.

In 1997, the IOM *Committee on the Evaluation of the DoD CCEP* evaluated the CCEP's approach to diagnosing and treating subjects with low-level exposure to nerve agents, concluded that the CCEP provides "an appropriate screening approach to the diagnosis of disease" and made eight recommendations for improvement [see IOM (1997a) for full report of findings and recommendations]:

- C improve documentation of screening used in Phase I for patients with psychological conditions;
- C improve documentation of neurological screening done during Phases I and II of the program;
- C give Phase I primary physicians access to a neurologist and a psychiatrist for referral;
- C gather and record more complete patient health histories, including personal and family histories, and occupational and environmental exposure histories;
- C standardize, across the services, U.S. military pre-deployment physical examinations;
- C increase the uniformity of CCEP forms and reporting procedures across health facility sites;

- provide written evidence, for each patient, that all organ systems were evaluated; and
- offer group education and counseling to soldiers and their families about exposure to toxic agents.

In 1997 the IOM *Committee on the Evaluation of the DoD CCEP* made further recommendations to the DoD regarding the CCEP concerning [see IOM (1997b) for full report of findings and recommendations]:

- diagnosis and treatment of medically unexplained symptom syndromes (e.g., chronic fatigue syndrome, fibromyalgia, and multiple chemical sensitivity);
- collecting information about stress (i.e., traumatic events);
- screening for depression and substance abuse;
- evaluation of implementation of the CCEP across facilities; and
- coordination with the DVA regarding ongoing treatment of patients and health care provider education.

The IOM *Committee on the Evaluation of the Department of Veterans Affairs Uniform Case Assessment Protocol* was established to:

- evaluate the adequacy of the protocol to diagnose the broad range of medical assessment needs of Gulf War veterans;
- evaluate implementation of the program, including the process for patient referrals;
- evaluate VA outreach activities; and
- evaluate VA provider education.

In 1998, the committee made eleven recommendations to the DVA, briefly summarized as follows [see IOM (1998d) for full report of the committee's findings and recommendations]:

- adopt a new diagnostic pathway, at all VA facilities, eliminating the distinction between Phases I and II and including periodic reevaluation of patients without a diagnosis;
- expand the initial evaluation of Gulf War veterans entering the registry program with new questions and tests recommended by a national panel of experts;
- develop clinical practice guidelines for the most common symptoms among Gulf War veterans, and the difficult-to-diagnose, ill-defined, or medically unexplained conditions;
- modify processes and procedures for specialty diagnosis and treatment;
- establish an evaluation feedback mechanism to improve performance;
- design and implement a patient-satisfaction questionnaire for Gulf War veterans;
- improve the consistency of health data reporting across VA facilities;
- develop a system to update individual patient information;
- develop informational pamphlets addressing concerns of Gulf War veterans;
- improve routine intake forms to more easily identify the war or conflict in which veterans served; and
- encourage, and provide opportunities for, participation by Registry, primary-care, and specialist health care providers in education programs related to Gulf War health issues and problems.

In May, 1995, the President established a 12-membered panel, the *Presidential Advisory Committee on Gulf War Veterans' Illnesses* (PAC), to review multiple issues related to Gulf War Illnesses, including : research; coordinating efforts; medical treatment; outreach; external reviews; risk factors; and chemical and biological weapons.

The PAC (1996b; 1997) generally concluded that "the government largely had acted in good faith in handling Gulf War veterans' health concerns in comparison to the post-Vietnam War era", but "took strong exception, however, to the Department of Defense's inquiries related to chemical and biological warfare agent investigations." The PAC (1996a; 1996b; 1997) made numerous recommendations to the DoD and the DVA regarding: outreach programs for veterans with health concerns; medical and clinical policies, protocols, and education programs; research on Gulf War illnesses; investigations into possible chemical or biological warfare agents during the Gulf War; and development of an intraagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peace-keeping missions.

Regarding the possible causes of illnesses among Gulf War veterans, the PAC (1996b; 1997) concluded:
"current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products." The PAC (1996b; 1997) acknowledged, however, that "some of these risk factors explain specific, diagnosed illnesses in a few Gulf War veterans, for example, leishmaniasis has been diagnosed in 32 individuals", and that "Prudence requires further investigation of some areas of uncertainty, such as the long-term effects of low-level exposure to chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors."

In response to a Presidential Advisory Committee recommendation, President Clinton, in 1998, created the Special Oversight Board for Department of Defense Investigations of Gulf War Chemical and Biological Incidents "to provide advice and recommendations based on review of DoD investigations into possible detections of, and exposures to, chemical or biological weapons agents and environmental and other factors that may have contributed to Gulf War Illnesses" (PSOB, 1998). This group held its first public hearing in November, 1998.

In November, 1997, the U.S. House of Representatives Committee on Government Reform and Oversight published a report of an investigation (initiated in March, 1996) into:

- "the status of efforts to understand the clusters of symptoms and debilitating maladies known collectively as 'Gulf War Syndrome'";
- the degree to which "Gulf War veterans were being diagnosed accurately, treated effectively and compensated fairly for service-connected disabilities"; and
- "whether the Gulf War research agenda was properly focused on the most likely, not just the most convenient, hypotheses to explain Gulf War veterans' illnesses."

The committee made eighteen recommendations in four areas: diagnosis, treatment, compensation, and research [see U.S. House of Representatives (1997) for full report of the committee's findings and recommendations]. The five research recommendations were:

- Congress should create or designate an agency independent from the Departments of Defense and Veterans' Affairs as the lead Federal agency responsible for coordination of all research into Gulf War veterans' illnesses and allocation of all research funds.
- The lead Federal agency on Gulf War veterans' illnesses should focus research on the evaluation and treatment of the common spectrum of neuroimmunological disorders known as Gulf War Syndrome, multiple chemical sensitivity, chronic fatigue syndrome, and fibromyalgia.
- DoD and DVA medical systems should augment research and clinical capabilities with regard to women's health issues and the health effects of combat service on women's health.
- DVA, in collaboration with NIH, CDC, FDA, and other public health agencies should establish an interdisciplinary research and clinical program on the identification, prevention, and treatment of environmentally induced neuropathies.
- FDA should grant a waiver of informed consent requirements for the use of experimental or investigational drugs by DoD only upon receipt of a Presidential finding of efficacy and need.

In 1997, The U.S. Senate Committee on Veteran Affairs established a staff of 20 experts and investigators, the *Special Investigation Unit on Gulf War Illnesses (SIU)*, to examine DoD's plans and policies, the intelligence community's role, health risks encountered by U.S. troops during the war, record keeping, and DVA's accountability to and responsibilities for Gulf War Veterans.

The SIU reviewed available written material, held hearings across the country, held site visits of DVA and DoD facilities, and met with government employees, veteran service organization representatives, health professionals, scientists, researchers, and Gulf War veterans and their families. The final report of the SIU was published recently (U.S. Senate, 1998). The SIU made four general recommendations:

- "Preparedness shortfalls for effective defense against battlefield hazards existed before and during the Gulf War and continue today."
- "Insufficient program monitoring hinders the Department of Defense's and Department of Veterans Affairs' effectiveness in serving Gulf War veterans."
- The Department of Defense's and Department of Veterans Affairs' failure to collect information, retain records, and generate valid data analysis impedes effective responses to Gulf War veterans." and
- "The Department of Defense and Department of Veterans Affairs must make ongoing cooperation and coordination a top priority to ensure timely and effective service for Gulf War veterans."

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